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Box Patent Application

Assistant Commissioner for Patents
Washington, DC 20231

Presented for filing is a new patent application claiming priority from a provisional patent application of:

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FRITZ A. BRAUER

Title: CUTTING AND CAUTERIZING SURGICAL TOOLS

Enclosed are the following papers, including those required to receive a filing date under 37 CFR 1.53(b):

	<u>Pages</u>
Specification	8
Claims	4
Abstract	1
Declaration	[To be Filed at a Later Date]
Drawing(s)	8

Enclosures:

— Postcard.

Under 35 USC §119(e)(1), this application claims the benefit of prior U.S. provisional application 60/175,772, filed January 12, 2000.

CERTIFICATE OF MAILING BY EXPRESS MAIL

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Signature

Derek W. Norwood

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04/10/00
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1859-1951

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08041-007001-044000

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Marital status	1.5	0.5	1	3
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Page 2

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EL 584940220US US

CUTTING AND CAUTERIZING SURGICAL TOOLS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of United States Provisional Patent Application No. 60/175,772, filed January 12, 2000.

BACKGROUND

5 The present invention relates generally to surgical tools, and more particularly, to surgical tools that can be used for cauterizing and cutting during a surgical operation.

 Bleeding commonly occurs during surgical procedures. Typically, the bleeding emanates from a bleeding vessel during a cutting procedure using, for example, a scalpel. The bleeding can greatly obscure surgeon's view. To control the bleeding, the vessel can be
10 clamped with a surgical instrument to stop the flow of blood, and the vessel can be mended. The mending, however, tends to cause infection and improper healing.

 More recently, electrocautery systems have been used to control bleeding from a vessel. An electrocautery system delivers an electrical current through a cable to an electrode, which is positioned at the bleeding site. A heat or energy source is used to
15 gradually increase the temperature of the electrode, which heats the tissue in order to heat the tissue surrounding the bleeding vessel. By heating the tissue, cauterization occurs at the point of bleeding.

 Known electrocautery systems are separate and distinct from the cutting tools used during surgical procedures. This means that a surgeon must constantly switch between the
20 cutting tool and the electrocautery system during an operation. Accordingly, this increases the risk of mistakes, makes the surgery more complex, and delays the surgical procedure.

 Thus, a need exists for surgical tools that allow a surgeon to perform cutting and cauterizing at an application site in which the cutting and cauterizing can be performed with the same surgical tool.

SUMMARY

25 In general, the invention is directed to an apparatus for cutting and cauterizing during a surgical procedure. The apparatus includes a surgical tool having a tip with one or more

edges for cutting, and at least one electrode coupled to at least a portion of the tip for cauterizing. A surgeon can thus perform cutting and cauterizing using the same surgical tool.

Accordingly, in one aspect, the invention is directed to a surgical tool having a tip with at least one mechanical cutting edge. At least one electrode is formed integral with the tip.

In another aspect, the invention is directed to a method for manufacturing a surgical tool that includes coupling a tip to a handle. The method also includes forming one cutting edge on the tip, and forming at least one electrode integral with the tip.

In another aspect, the invention is directed to a surgical tool that includes a housing and a tip formed from an electrically conductive material. A cutting edge is bonded to the tip.

In yet another aspect, the invention is directed to a surgical tool that includes a tip having a mechanical cutting edge in which the tip is coupled to a handle. A push/pull device is formed integral with the handle, and an electrode is coupled to the distal end of the push/pull device. The electrode passes across a surface of the tip, when the push/pull device is actuated.

In yet another aspect, the invention is directed to a system for cutting and cauterizing that includes a surgical tool having a tip coupled to a handle, the tip includes a mechanical cutting edge and an electrode formed integral with the tip; and an energy source coupled to the handle to deliver electrocautery energy to the tip via a contact electrode passing through the handle.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1A illustrates a bifacet tip in a first embodiment.

FIG. 1B illustrates a lance or spear tip in a first embodiment.

FIG. 2A illustrates the bifacet tip of FIG. 1 A in a second embodiment.

FIG. 2B illustrates the lance or spear tip of FIG. 1B in a second embodiment.

FIG. 3 illustrates the bifacet tip of FIG. 1A in a third embodiment.

FIG. 4 illustrates a surgical tool coupled to an energy source in accordance with the present invention.

FIG. 5A illustrates the bifacet tip of FIG. 1A in a fourth embodiment.

FIG. 5B illustrates the lance or spear tip of FIG. 1B in a third embodiment.

5 FIG. 6 illustrates the bifacet tip of FIG. 1A in a fifth embodiment.

FIG. 7 illustrates the bifacet tip of FIG. 1A in a sixth embodiment.

FIG. 8 illustrates the surgical tool of FIG. 4 having a push/pull device.

FIG. 9 illustrates the surgical tool of FIG. 4 having a removable device.

DETAILED DESCRIPTION

10 In general, the invention is directed to an apparatus for cutting and cauterizing during a surgical procedure. The apparatus includes a surgical tool having a tip with one or more edges for cutting, and one or more electrodes formed on at least a portion of the tip for cauterizing. The cutting edge preferably has a sharpness suitable for making incisions or for cutting tissue. The electrode can be used to pass electrocautery energy to an incision site to control bleeding.

15 The invention is based on a principle different from known surgical tools for cauterizing and cutting that are used in industrial and medical applications. The apparatus does not use an electrode from a separate electrocautery system to cauterize an area around the incision site; rather, the apparatus includes an electrode formed on at least a portion of the tip to deliver electrocautery energy from an energy source virtually simultaneously during a cutting procedure. The cautery and cutting can thus be performed using the same surgical tool.

20 Unless otherwise defined, all technical and scientific terms used herein have substantially the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although many methods and materials similar or equivalent to those described herein can be used in the practice or manufacturing of the present invention, suitable materials and configurations are described below.

25 Surgical tools for mechanical cutting can be made with tips with multiple facets to form multiple types of cutting edges. For example, the tip can be "bifacet" (FIG. 1A), or "lance or spear" (FIG. 1B).

FIG. 1A shows a bifacet tip 1 with beveled edge 4 and a face 6. The edge 4 may be used for cutting during a surgical procedure. The edge 4 and the face 6 form an apex 8, which may be used for piercing. Preferably, the edge 4 has a sharpness suitable to cut tissue or make incisions.

5 A portion of the tip 1 may be covered with one or more electrodes 10. In one configuration, as shown in FIG. 1A, the electrodes 10 are formed on both sides of the tip 1 such that only the edge 4 and the face 6 are exposed. The electrodes 10 may be formed from current carrying metals, such as titanium, platinum, copper, nickel, tin, gold, chromium, iron, silver, or other similar conductive metals or alloys. The electrodes 10 may also be formed
10 from current carrying ceramic materials, such as titanium nitride, silicon carbide, or tungsten carbide. Alternatively, as shown in FIG. 2A, the electrodes 10 may be formed on only a portion of the tip 1. The electrical conductors 10 may be applied to one or more surfaces of the tip 1 by painting, vapor deposition, chemical coating, adhesively bonding or other similar techniques.

15 In another configuration, as shown in FIG. 3, the tip 1 may be formed to include a facet 13 formed from diamond and a portion 17 formed from electrically conductive material, such as tungsten nitride, that is deposited onto the surface of the tip 1. In this configuration, the portion 17 may be used to deliver energy to the incision site. The tip 1, in FIG. 3, may optionally include the electrodes 10. In other configurations, the tip 1 may be formed from
20 any combination of materials listed in Table 1 below. Thus, for example, the tip 1 could be formed from a conductive steel and also include a cutting edge 4 made from, for example, diamond. In this case, the cutting edge 4 could be bonded to a conductive steel portion 17 of the tip 1 by glue.

FIG. 1B illustrates a tip 50 similar to the tip 1. The tip 50, however, includes two
25 beveled edges 54, 56 to form a lance or spear. The edges 54, 56 can be used to cut, and the apex 58 can be used to pierce. Similar to the tip 1, the tip 50 may include one or more electrodes 65 formed on both sides of the tip 50 such that the edges 54, 56 are exposed (FIG. 1B). Alternatively, the electrode 65 may be formed on only a portion of the tip 50 (FIG. 2B).

The edges 4, 54, 56 may have a sharpness of about $1\mu\text{m} - 25\text{ nm}$. Table 1 below lists
30 examples of various materials from which the tips 1, 50 can be formed.

TABLE I				
MATERIAL	HARDNESS Moh; Knoop (kg/mm ²)	THERMAL CONDUCTIVITY (W/cm • K)	SPECIFIC HEAT (J/g • K)	FLEXURE STRENGTH (MPa)
diamond (IIa)	10; 7000-10,000	5-25	0.52	2940
silicon carbide	9.5; 2480-3500	4.5-4.9	0.67-0.69	250
sapphire	9; 1370-2250	0.23-0.46	0.75-0.78	1200
tungsten carbide	8.5-9.5; 1800-3000	0.63	~0.3	~2000
steels	5-8.5	0.14-0.85	0.45	800

The "hardness" value can be used to determine a material's resistance to wear. The "strength" value can be used to determine a material's resistance to fracture or plastic deformation. The "flexure strength" can be used to determine how easily the material can be sharpened. If the flexure strength is not sufficient, a material may bend or break during sharpening. The "specific heat" can be defined as heat capacity. Combining the specific heat and "thermal conductivity" values, it can be determined how quickly a material may warm during a surgical procedure. The thermal conductivity value can be used to determine how quickly energy can pass to, for example, a heat sink coupled to the tips 1, 50. The specific heat value can be used to determine a temperature rise of the material, once a portion of the energy has passed to the heat sink.

FIG. 4 diagrammatically illustrates an example of a cutting and cauterizing surgical tool 100. The surgical tool 100 includes a handle 120. For simplicity, the following discussion will assume that the tip 1 is coupled to the member 101. However, the tip 50 or other similar tips can also be used.

Referring again to FIG. 4, the tip 1 is coupled to the distal end 110 of the handle 120. Passing through the handle 120 is a contact electrode 130. Preferably, the contact electrode 130 is configured to be in electrical contact with the electrodes 10 formed on the tip 1. In one configuration, the contact electrode 130 is formed from 300-series stainless steel that is passivated or gold plated.

In FIG. 4, the contact electrode 130 extends substantially from the distal end 120 to the proximal end 140 of the handle 120. Attached to the proximal end 140 of the contact electrode 130 is a cable 150. The cable 150 is preferably connected to an energy source 170. Suitable energy sources are, for example, a Bovie™ generator.

The source 170 may include a pedal 175 and a cable 180. The cable 180 may be coupled to a return electrode 181 situated on or under the patient's body. The switch 175 may be used by a surgeon to manually turn on and off the energy source 170. Alternatively, the source 170 may be activated automatically, for example, in predetermined time intervals.

5 In operation, the surgeon presses the switch 175. This activates the source 170. The source 170 then delivers an electrical current to the contact electrode 130 via the cable 150. The electrical current may be increased by, for example, repeatedly pressing the switch 175. Once the electrical current is passed to the contact electrode 130, the current then passes to the electrodes 10 on the tip 1. The current then passes through the patient's body to the cable 10 180 via the return electrode 181. This configuration thus forms a complete electrical circuit. In this way, the surgeon can use the non-cutting edges of the tip 1 to cauterize at the incision site. Additionally, a surgeon can also perform cutting procedures using the tip edge 4 and apex 8. The surgeon can thus use the same surgical tool to perform both cutting and cauterizing, without having to switch between separate surgical tools, as in known systems.

15 During cutting procedures, electromagnetic radiation, for example, from a laser, may be delivered through the handle 120. The radiation may be delivered using a waveguide (not shown) or other similar device. The radiation may be emitted through the edge 4 and the face 6. For the tip 50, the radiation may be emitted through the edges 54, 56.

20 FIG. 5A illustrates the tip 1 in a fourth embodiment. In FIG. 5A, a conductor 200 slides parallel to the face 6, and across a surface 7 of the tip 1. The electrodes 10, in this embodiment, may be optional. FIG. 5B shows the tip 50 in a third embodiment. In FIG. 5B, the conductor 200 slides across a surface 55 of the tip 50. The tip 50 may optionally include the electrodes 65.

25 FIG. 8 shows an example of a push/pull device 204 for sliding the conductor. FIG. 8 shows the tip 1 coupled to the handle 120 with the integrated push/pull device 204. Alternatively, the tip 1 could be replaced with the tip 50 and also be used with the device 204. The device 204 includes a body 206 and a projection 208. The conductor 200 is coupled to a distal end 209 of the body 206. The contact electrode 130 is coupled to a proximal end 211 of the body 206. In this configuration, the contact electrode 130 and the 30 electrode 200 are electrically coupled together inside the body 206, such that electrocautery energy can be delivered to the electrode 200.

In operation, a surgeon can move the electrode 200 to, and from the application site using the projection 208. For example, a surgeon can manually push the projection 208 toward the tip 1. This causes the electrode 200 to travel toward the application site across the surface 7. Conversely, the surgeon can retract the electrode 200 by sliding the projection 208 in a direction away from the application site.

FIG. 6 illustrates an electrode 300 bonded parallel to the face 6 on the surface 7. The electrode 300 may have a diameter of about 0.6 mm or less. The electrode 300 may be formed from materials similar to the electrodes 10. The electrode 300 forms an electrical contact with the contact electrode 130 similar to the electrodes 10. In this configuration, the electrodes 10 may be optional. The electrode 300 may be a wire electrode.

FIG. 7 illustrates an electrode 400 formed integral with the tip 1. The electrode 400 is embedded in a cavity 16 of the tip 1. The electrode may be about 0.25 mm or less. An insulation layer 18 may cover at least a portion of the electrode 400. The electrode 400 may be a wire electrode. Similar to the electrode 300, the electrode 400 forms an electrical contact with the contact electrode 130. The cavity 16 may also be filled with suitable bonding or filling material to secure the electrode 400 inside the cavity 16.

In another configuration, the surgical tool 100 may include a removable device 500. The device 500 includes the tip 1 rigidly attached to a plug 506. The plug 506 includes a locking clip 507 to secure the tip 1, and a pin 504 coupled to the locking clip 507 with a mount 509. The pin 504 is coupled to the tip 1 via the plug 506, such that the pin 504 is in electrical communication with the electrodes 10 on the tip 1. The pin 504 is configured to frictionally engage the handle 120 through an opening 510. When the pin 504 frictionally engages the handle 120, the pin 504 can electrically communicate with the electrode 130. As a result, electrical current from the source 170 can be delivered to the electrodes 10 via the electrode 130 and the pin 504.

Preferably, the surgical tool 100 (FIG. 9) also includes a button 503 formed integral with the handle 120. The button 503 is configured to allow a surgeon to deliver electrical current to the tip 1 via the electrode 130 by pressing the button 503. In this way, the surgeon can immediately and simply deliver electrical current to the application site to cauterize without having to use a separate electrocautery system. Further, the removable device 500 allows a surgeon to easily replace the tip 1 with a sharper or different tip.

The preferred configurations for the surgical tool 100 and the tips 1, 50 are inexpensive, simple, robust, and efficient. A surgeon can cut and cauterize using the same tool. Thus, separate surgical tools are not required, as in known systems. Further, the preferred surgical tools can be used for monopolar and bipolar electrocautery applications.

5 This can be done by operating the electrodes 10, 65, 200, 300, and 400 at different potentials from the contact electrode 130. Additionally, the preferred surgical tool 100 is versatile. Depending on the application, the electrodes can optionally be formed on the tip, brazed to an edge of the tip, embedded in the tip, or retracted to and from the tip. Alternatively, the tip can be formed from a conductive member with a cutting edge bonded thereto. Further, the
10 electrodes can be removed and replaced, by, for example, acid etching, such that the same tip can be used for multiple applications. A cooling mechanism may be coupled to the surgical tool to cool the tip during cutting or cauterizing.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and
15 scope of the invention. For example, a non-stick coating may be placed on at least a portion of the electrodes to minimize or prevent tissue from sticking to the tip. Suitable coatings include fluoropolymers, such as TeflonTM, ceramic titanium alloys, and ceramics including transition metals, such as titanium nitride. Moreover, the electrodes 10, 65, 200, 300, and 400 may be removed from the tips 1, 50 by acid etching and can be coated with a friction
20 reducing compound, such as TeflonTM, ParyleneTM, or other compounds, which can prevent the adhesion of cauterized tissue to the cutting edges.

WHAT IS CLAIMED IS:

- 1 1. A surgical tool, comprising:
2 a tip having at least one mechanical cutting edge; and
3 at least one electrode formed integral with the tip.
- 1 2. The surgical tool of claim 1, wherein the at least one electrode comprises one of
2 titanium, platinum, copper, nickel, tin, gold, chromium, iron, and silver.
- 1 3. The surgical tool of claim 1, wherein the at least one electrode comprises at least one
2 wire rod, the wire rod having a thickness of about 0.25 mm.
- 1 4. The surgical tool of claim 1, wherein the tip further comprises a cavity and wherein
2 the at least one electrode comprises a wire rod embedded in the cavity.
- 1 5. The surgical tool of claim 1, wherein the at least one electrode further comprises a
2 non-stick coating.
- 1 6. The surgical tool of claim 5, wherein the non-stick coating comprises one of
2 fluoropolymers, ceramic titanium alloys, and ceramics.
- 1 7. The surgical tool of claim 4, wherein the at least one electrode comprises a wire rod,
2 the wire rod having a thickness of about 0.6 mm.
- 1 8. The surgical tool of claim 1, wherein the tip comprises one of silicon carbide,
2 tungsten carbide, sapphire, steel, and diamond.
- 1 9. The surgical tool of claim 1, wherein the at least one electrode comprises a friction
2 reducing compound.
- 1 10. The surgical tool of claim 1, wherein the surgical tool further comprises a contact
2 electrode in electrical communication with the at least one electrode.
- 1 11. The surgical tool of claim 1, wherein the tip comprises one of a lance and bifacet
2 edge.

1 12. The surgical tool of claim 1, wherein the at least one electrode comprises one of
2 titanium nitride, silicon carbide, or tungsten carbide.

1 13. A method of manufacturing a surgical tool, comprising:
2 coupling a tip to a handle;
3 forming at least one cutting edge on the tip; and
4 forming at least one electrode integral with the tip.

1 14. The method of claim 13, further comprising coupling a contact electrode to the handle
2 and establishing an electrical communication with the at least one electrode.

1 15. The method of claim 14, further comprising coupling an energy source to the contact
2 electrode and delivering an electrical current to the at least one electrode through the contact
3 electrode.

1 16. The method of claim 13, further comprising applying a non-stick coating to the at
2 least one electrode.

1 17. The method of claim 13, further comprising applying a friction reducing coating to
2 the at least one electrode.

1 18. The method of claim 13, wherein the forming step further comprises forming a
2 cavity in the tip and embedding the at least one electrode in the cavity.

1 19. The method of claim 13, wherein the forming step further comprises bonding the at
2 least one electrode to an edge of the tip.

1 20. The method of claim 13, further comprising removing the at least one electrode by
2 acid etching.

1 21. The method of claim 13, further comprising coupling the tip to a locking mechanism.

1 22. The method of claim 13, further comprising coupling the tip to a cooling mechanism.

1 23. The method of claim 15, further comprising delivering the electrical current through
2 an edge of the tip.

1 24. A surgical tool, comprising:
2 a housing; and
3 an electrically conductive tip coupled to the housing, the tip having a mechanical
4 cutting edge bonded to a portion of the tip.

1 25. The surgical tool of claim 24, wherein the tip further comprises one of tungsten
2 carbide, silicon carbide, sapphire, steel, and diamond.

1 26. The surgical tool of claim 24, wherein the at least one electrode comprises one of
2 titanium nitride, silicon carbide, or tungsten carbide.

1 27. A surgical tool comprising,
2 a tip coupled to a handle, the tip including a diamond cutting edge;
3 and a plurality of electrodes formed on a surface of the tip, the plurality of electrodes
4 not covering the cutting edge.

1 28. A surgical tool, comprising:
2 a tip having a mechanical cutting edge, the tip being coupled to a handle;
3 a push/pull device formed integral with the handle; and
4 an electrode coupled to a distal end of the push/pull device, the electrode passing
5 across a surface of the tip, when the push/pull device is actuated.

1 29. A system for cauterizing and cutting, comprising:
2 a surgical tool having a tip and a handle coupled to the tip, the tip including a
3 mechanical cutting edge and at least one electrode formed integral with the tip;
4 a contact electrode passing through the handle and electrically coupled to the at least
5 one electrode; and
6 an energy source coupled to the handle to delivery electrocautery energy to the at
7 least one electrode via the contact electrode.

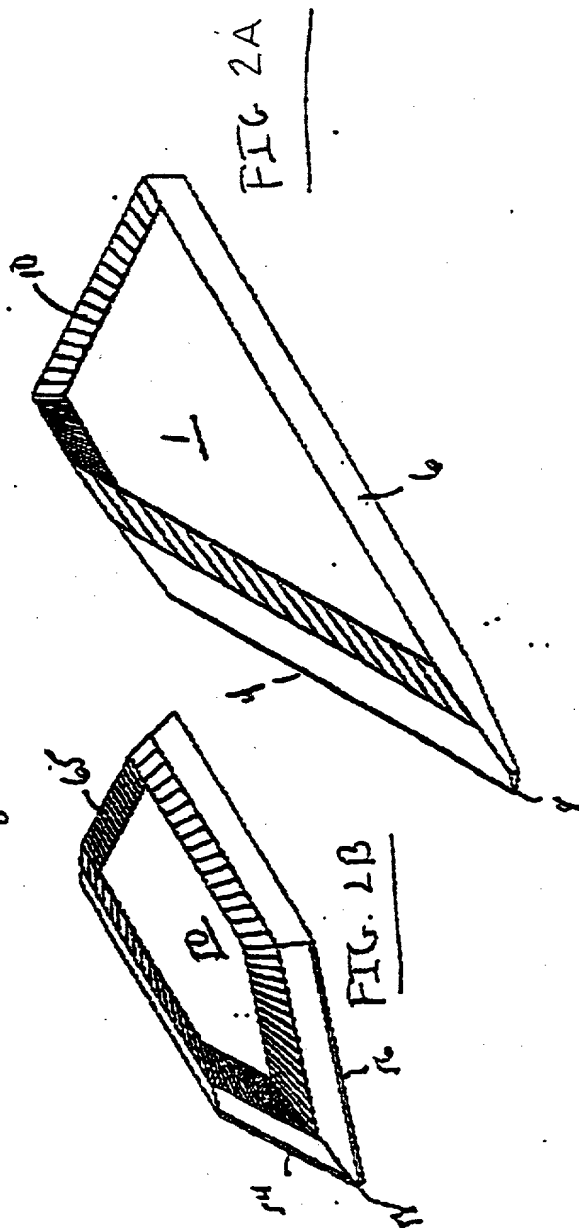
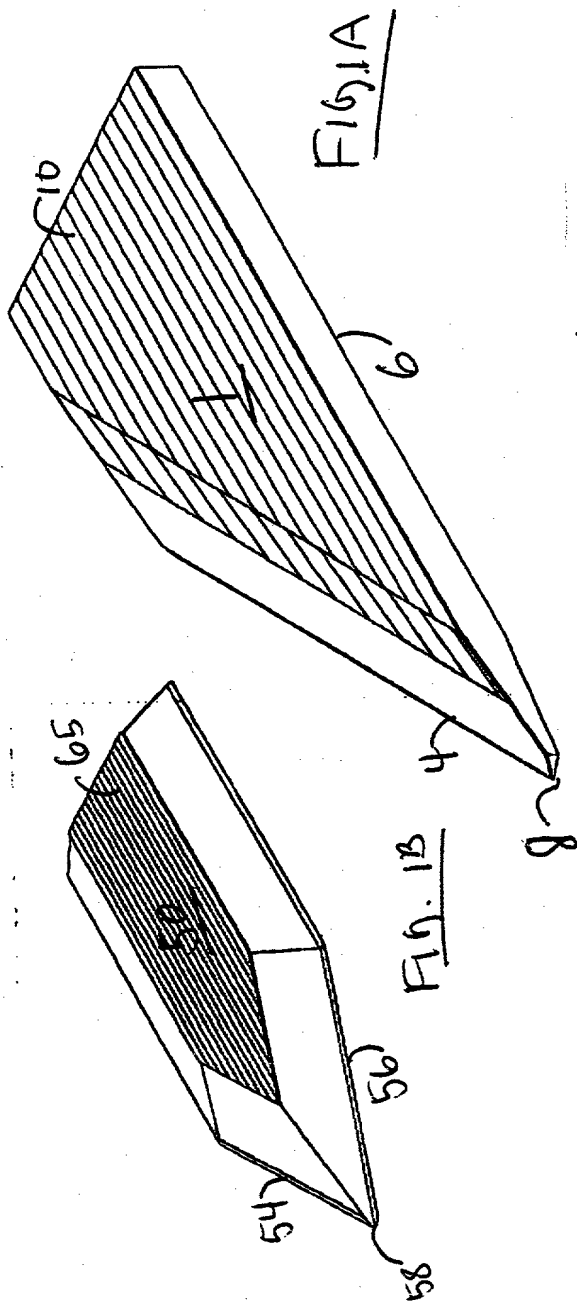
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31. The surgical tool of claim 30 further comprising a button formed integral with the handle and an energy source in electrical communication with the contact electrode.

ABSTRACT

A surgical tool that can be used for both cauterizing and cutting during a surgical procedure. The surgical tool may include a tip having an edge for cutting and electrodes formed at or near the edge for cauterizing. The electrodes are configured to be in electrical contact with a contact electrode passing through a handle of the surgical tool. An electrical current may be passed through the contact electrode to the electrodes formed at or near the edge of the tip.

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FIG. 3

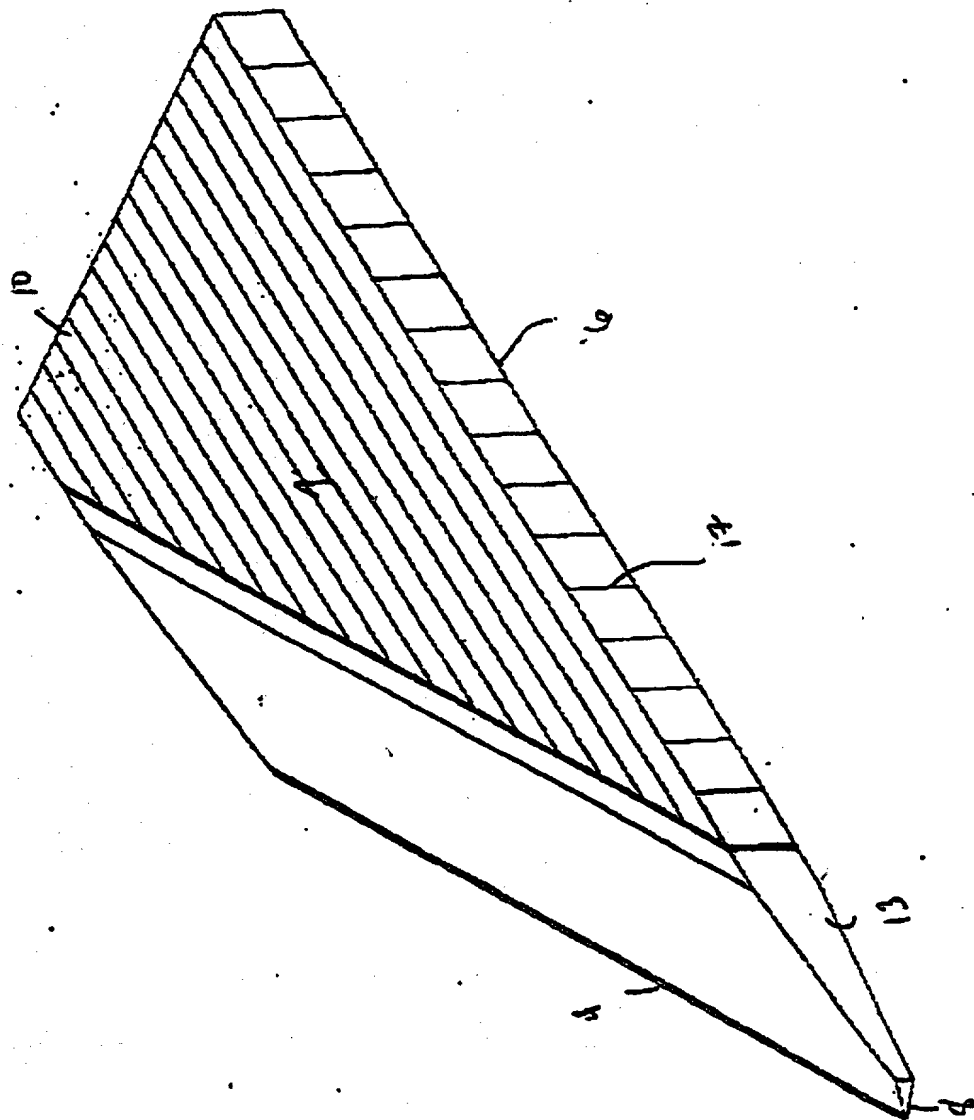
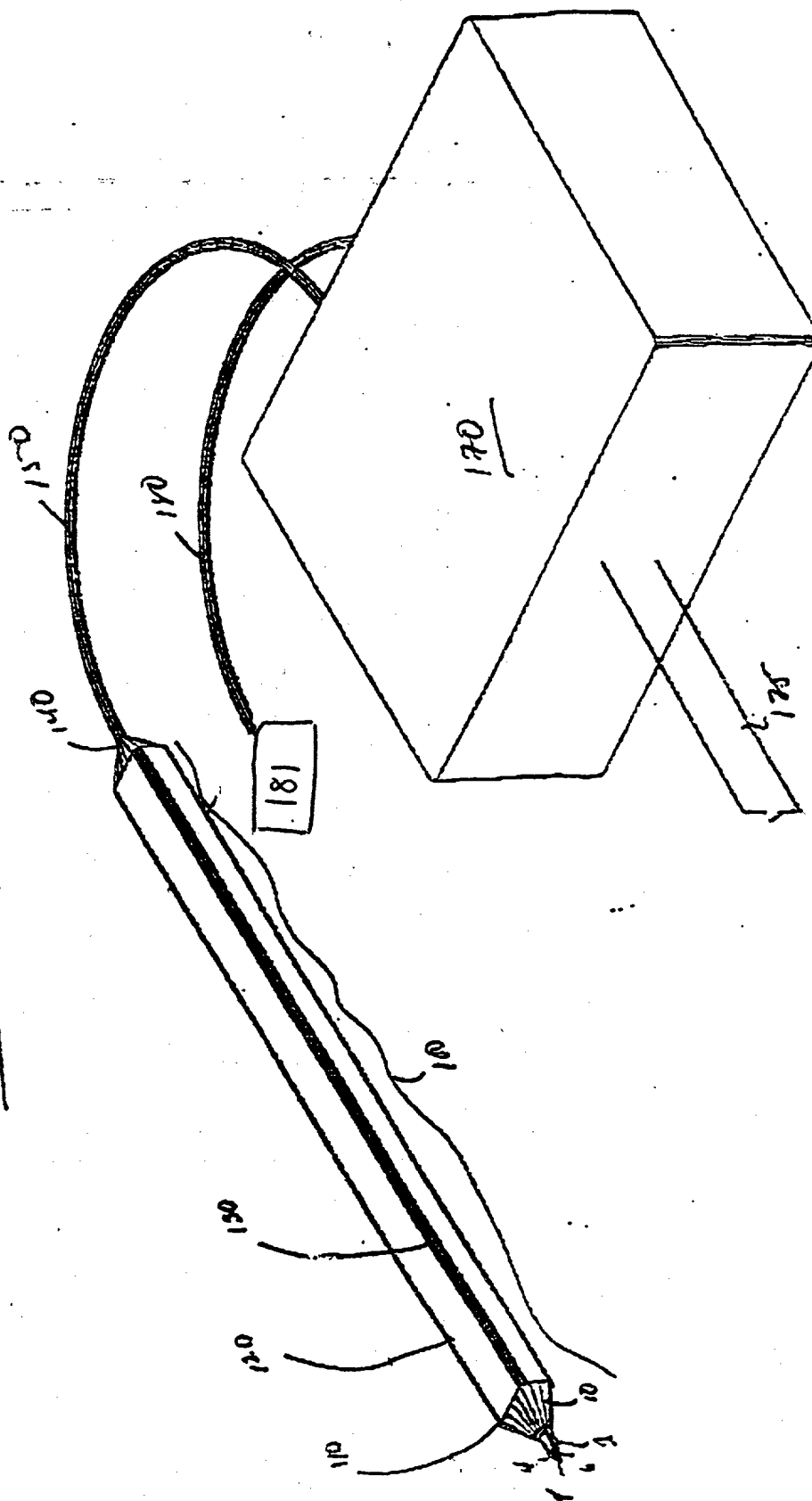
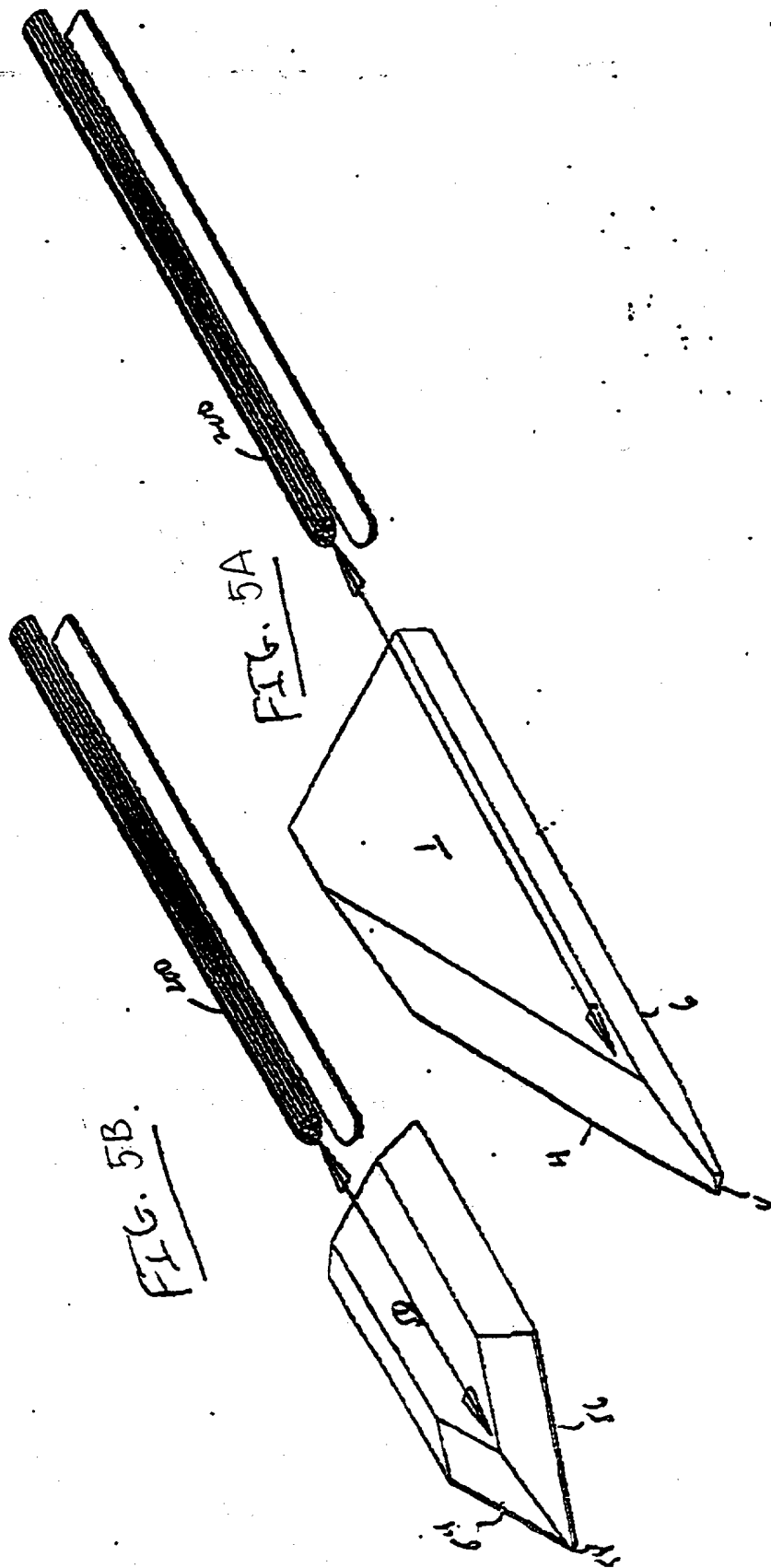


FIG. 4





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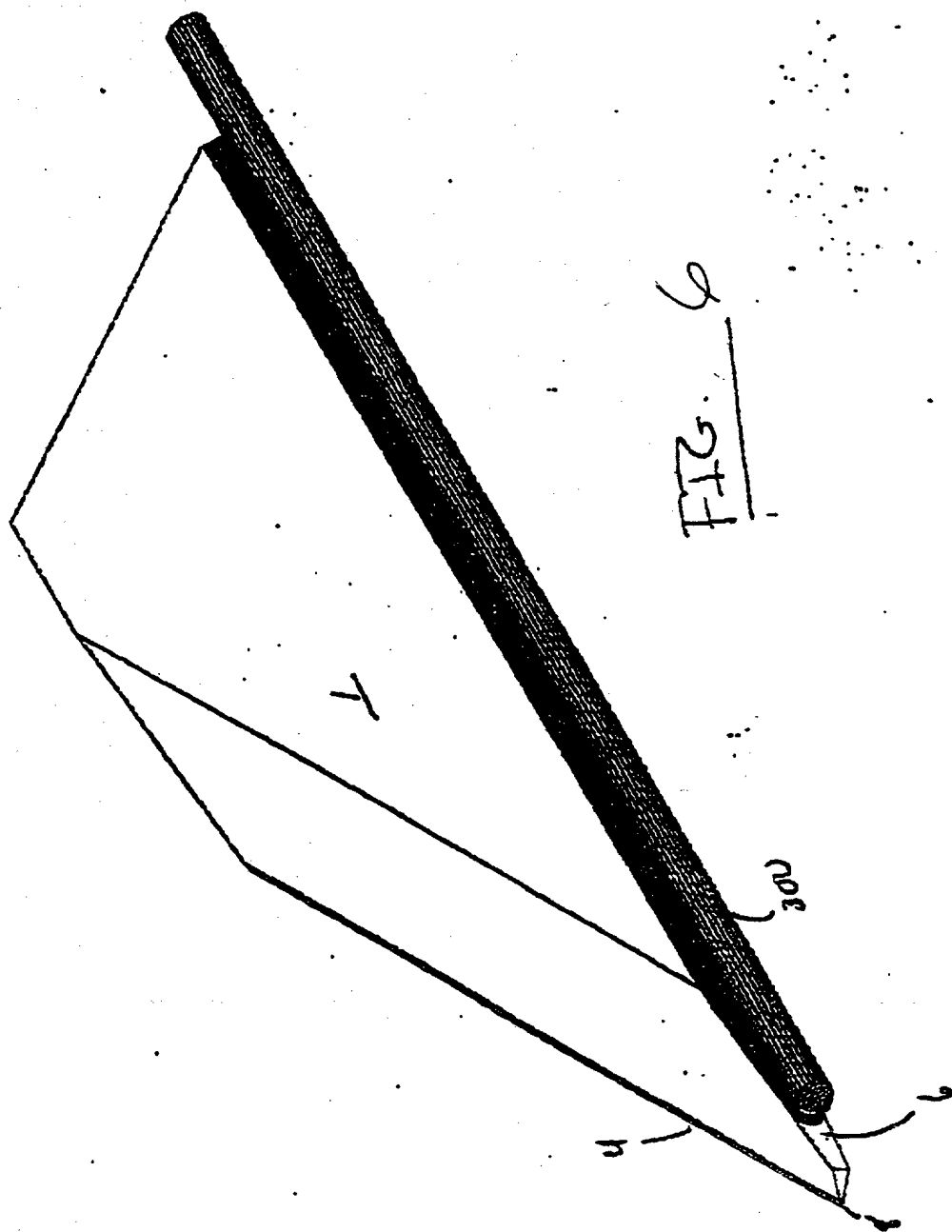
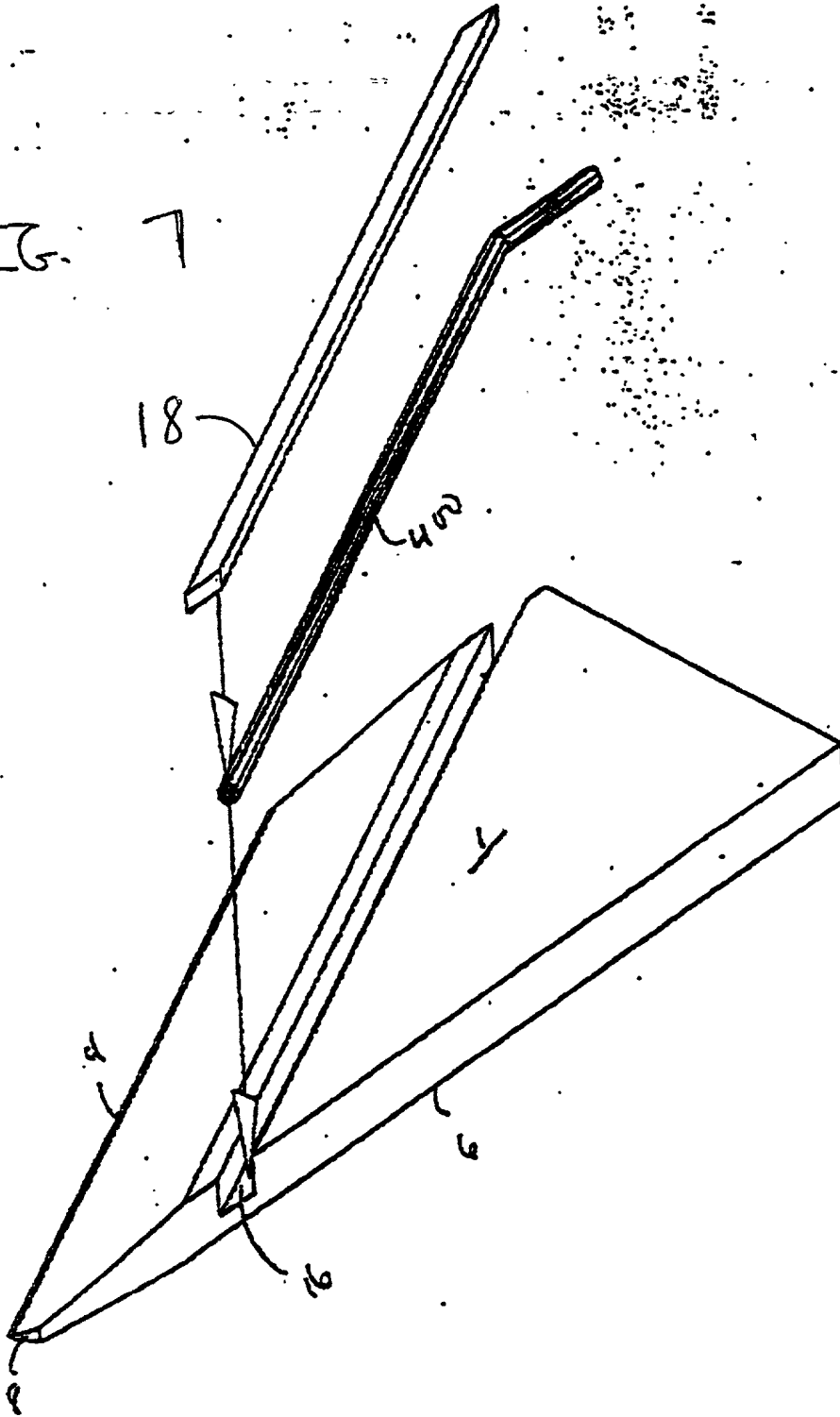
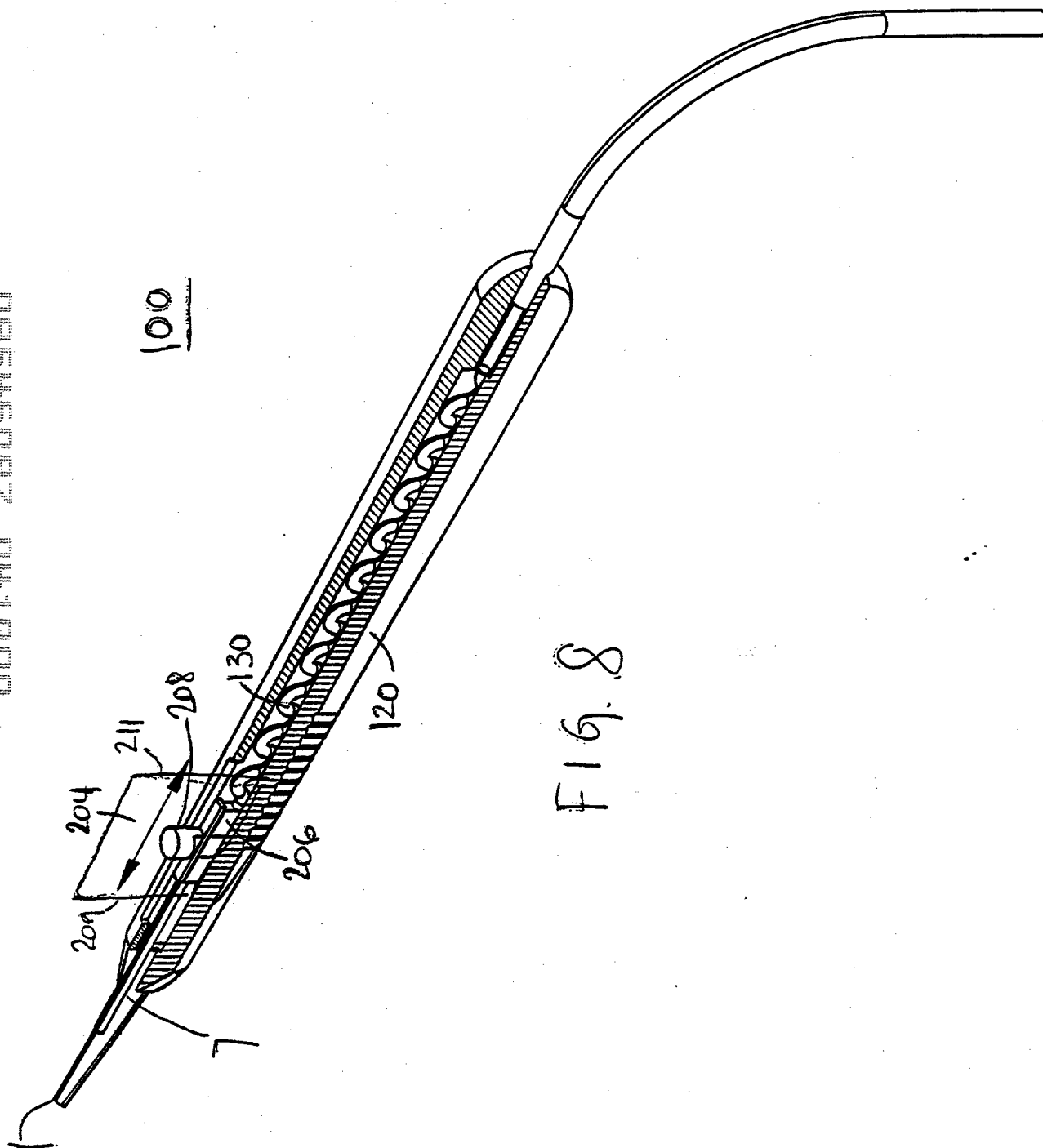


FIG. 6

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FIG. 7





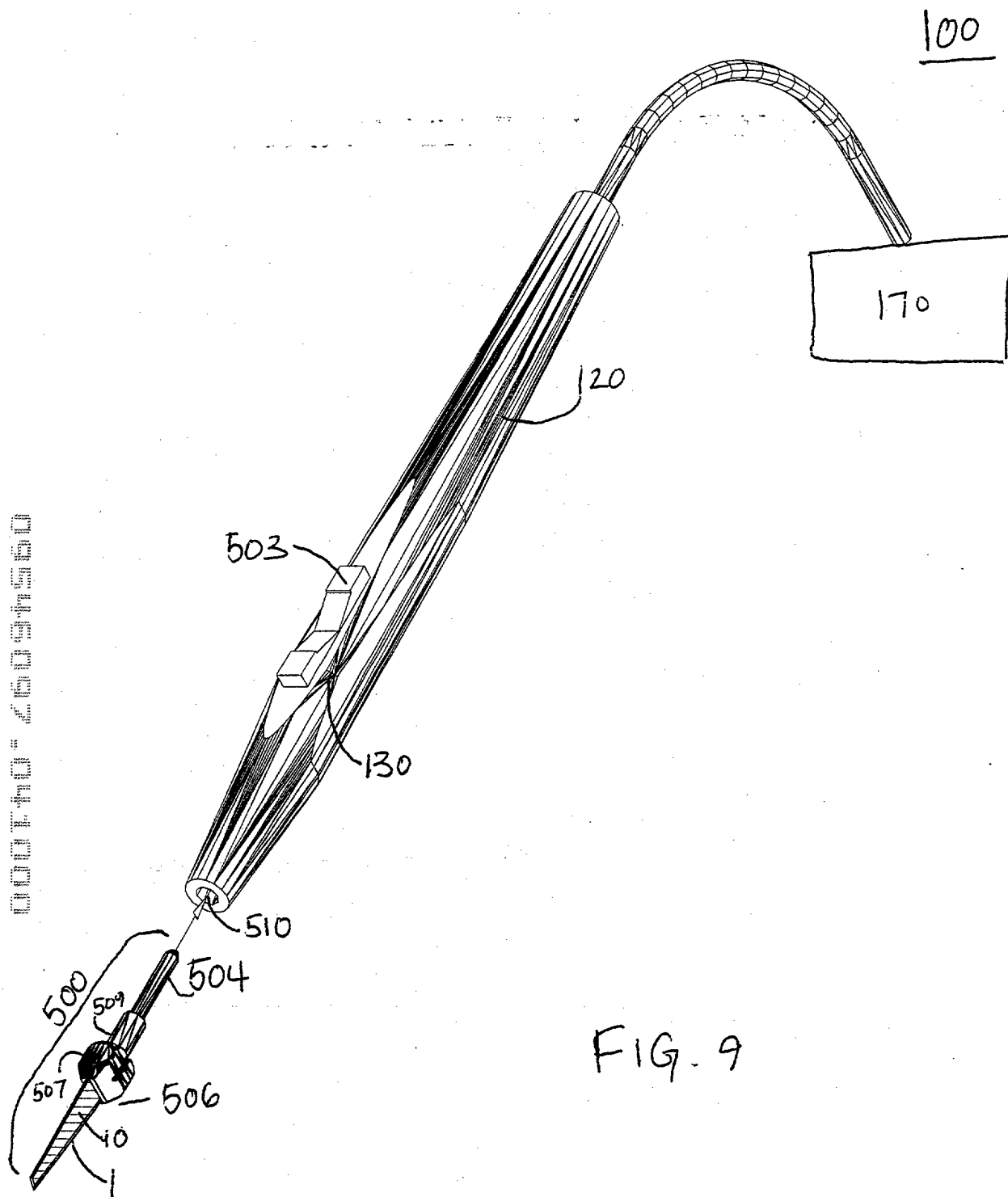


FIG. 9

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled CUTTING AND CAUTERIZING SURGICAL TOOLS, the specification of which:

- ☐ is attached hereto.
☒ was filed on April 10, 2000 as Application Serial No. and was amended on .
☐ was described and claimed in PCT International Application No. filed on and as amended under PCT Article 19 on .

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information I know to be material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim the benefit under Title 35, United States Code, §119(e)(1) of any United States provisional application(s) listed below:

U.S. Serial No.	Filing Date	Status
60/175,772	January 12, 2000	Pending

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information I know to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Serial No.	Filing Date	Status
-----------------	-------------	--------

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

Country	Application No.	Filing Date	Priority Claimed
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No

Combined Declaration and Power of Attorney

Page 2 of 2 Pages

I hereby appoint the following attorneys and/or agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

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